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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/991,854      | 11/14/2001  | Avi J. Ashkenazi     | P2730P1C24          | 3241             |

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EXAMINER

LANDSMAN, ROBERT S

ART UNIT PAPER NUMBER

1647

DATE MAILED: 10/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/991,854

**Applicant(s)**

GENENTECH, INC.

**Examiner**

Robert Landsman

**Art Unit**

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 September 2004.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 119-121 and 123 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 119-121 and 123 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 9/9/04.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***1. Formal Matters***

- A. The Amendment dated 9/9/04 has been entered into the record.
- B. Claims 119-124 were pending. Claims 122 and 124 have been canceled. Therefore, claims 119-121 and 123 are pending and are the subject of this Office Action.
- C. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

### ***2. Priority***

- A. Applicant asserts that PCT/US00/05841, filed March 2, 2000 discloses a MLR (mixed lymphocyte reaction) assay and that the data generated in the MLR assay establish patentable utility. Applicants also argue that the presently claimed SEQ ID NOs were first disclosed in US Application 60/097,661, filed 8/24/98. However, a review of the instant application and this assay do not lead to a conclusion of utility based on this assay, and therefore, priority to this PCT and/or provision application is not afforded for the reasons of record. The effective filing date of the instant application is still based on present application, filed 11/24/01 for the reasons of record.

### ***3. Information Disclosure Statement***

- A. The Information Disclosure Statement dated 9/9/04 has been entered into the record. All references have been considered.

### ***4. Specification***

- A. All objections to the specification have been withdrawn in view of Applicants' amendments.

### ***5. Claim Objections***

- A. The objection to claims 119-122 and 123 has been withdrawn in view of Applicants' amendments to the claims.

### ***6. Claim Rejections - 35 USC § 101***

- A. Claims 119-121 and 123 remain rejected under 35 USC 101 for the reasons already of record on pages 3-5 of the Office Action dated 3/9/04. Applicants have submitted a Declaration under 37 CFR

1.132 by Dr. Fong. However, this Declaration is insufficient to overcome the holding of lack of utility based on results of the MLR assay. At paragraph #8 of the Declaration, Dr. Fong states “[t]he MLR assay of the present application is designed to measure the ability of a test substance to “drive” the dendritic cells to induce the proliferation of T-cells that are activated, or co-stimulated in the MLR, and thus identifies immune stimulants that can boost the immune system to respond to a particular antigen that may not have been immunologically active previously”. This is not what the instant specification asserts at pages 204-206. There is no mention in the instant specification about boosting the immune system “to respond to a particular antigen that may not have been immunologically active previously”. It would appear that Dr. Fong is reading the results of the Peterson et al. reference into the disclosure of the instant specification. However, the Peterson et al. reference was not available at the time the instant application was filed, therefore, reliance on the methods and results of this reference is improper.

In paragraph #9 of the Declaration, Dr. Fong states that IL-12 was first identified in an MLR in Gubler et al. (PNAS 88: 4143-4147, 1991). However, a review of Gubler et al. does not reveal the use of MLR in evaluating the biological effects of IL-12. Gubler et al. teach that IL-12 is produced by peripheral blood lymphocytes (predominantly B cells) under appropriate conditions and that IL-12 activates NK cells, facilitates the generation of specific allogeneic CTL responses and stimulates secretion of gamma-interferon. Additionally, IL-12 synergizes with IL-2 to cause the proliferation of resting peripheral blood lymphocytes. Therefore, the further work of researchers regarding IL-12 was not based on the results of a single assay, being the MLR, but rather by a body of work which provides for a number of biological activities of IL-12 which are not disclosed for the claimed invention. The claimed invention is not IL-12. Secondly, the methods of Peterson et al. are not disclosed in the instant specification and are after the filing date of the instant application.

In paragraph 10 of the Declaration, Dr. Fong asserts “a PRO polypeptide shown to stimulate T-cell proliferation in the MLR assay of the present invention with an activity of at least 180% of the control is expected to have the type of activity as that exhibited by IL-12”. This is an assertion not supported by any facts or evidence of record. First, the instant specification fails to disclose the degree of activity for the claimed invention in the MLR assay. The specification states that any positive increase over control is considered positive. Therefore, there is no disclosure that the activity in the assay was at least 180%. Secondly, there is no evidence of record which correlates an activity of at least 180% of control as predictive of an activity of IL-12. It is not clear from what data this conclusion is derived. Therefore, the Declaration is not persuasive to overcome the holding of a lack of utility for the claimed invention based on the MLR assay. It is believed that all pertinent arguments have been addressed.

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**7. Claim Rejections - 35 USC § 112, first paragraph - enablement**

A. Claims 119-121 and 123 remain rejected under 35 USC 112, first paragraph, for the reasons already of record on page 6 of the Office Action dated 3/9/04. Applicants argue that the present invention is enabled since it possessed utility under 35 USC 101. This argument has been considered, but is not deemed persuasive for the reasons given in the above rejection under 35 USC 101.

**7. Claim Rejections - 35 USC § 112, second paragraph**

A. All rejections under 35 USC 112, second paragraph, have been withdrawn in view of Applicants' arguments or amendments to the claims.

**8. Claim Rejections - 35 USC § 102**

A. The rejection of claims 119-121 and 123 under 35 USC 102 as being anticipated by Baker et al. has been withdrawn in view of the fact that this reference is Applicants' own work and does not disclose, or teach, any more with regard to enablement or utility than that of the present invention.

B. Claims 119-121 and 123 remain rejected under 35 USC 102 as being anticipated by Fernandez for the reasons already of record on page 7 of the Office Action dated 3/9/04. Applicants argue that, based on the priority date of the present invention, Fernandez is not prior art. This argument has been considered, but is not deemed persuasive since the priority date of the present invention remains 11/24/02 as discussed above.

C. The rejection of claims 119-121 and 123 under 35 USC 102 as being anticipated by Zhao et al. has been withdrawn in view of the fact that this reference only teaches a protein which overlaps the protein of the present invention by 8 residues. The Examiner cannot make a prima facie case that the antibodies of Zhao would have bound to this region of the protein of Zhao. Therefore, it is not clear that Zhao teach antibodies which would bind to the protein of the present invention.

**9. Claim Rejections - 35 USC § 103**

A. The rejection of claims 119-121 and 123 under 35 USC 103 as being unpatentable over Zhao et al. in view of Fernandez has been withdrawn for the reasons seen above for Zhao under 35 USC 102.

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**10. Conclusion**

A. No claim is allowable.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

***Advisory information***

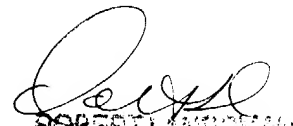
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (571) 272-0888. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961.

Official papers filed by fax should be directed to (703) 872-9306. Fax draft or informal communications with the examiner should be directed to (571) 273-0888.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-0700.

Robert Landsman, Ph.D.  
Patent Examiner  
Group 1600  
October 04, 2004

  
ROBERT LANDSMAN  
PATENT EXAMINER